REMARKS

Claims 1 to 9, 11 to 24 and 29 to 45 are in the case.

Claim 1 has been editorially revised to better clarify certain elements of the apparatus and their location. The claim has also been amended to overcome the objection set forth in Paragraph 1 of the Office Action — the term "penetrable closure" has now been changed to read "penetrable seal".

New Claims 30 to 45 have been added to the application. Claims 30 to 45 are dependent on Claim 29 and are believed to be allowable for the reasons advanced below regarding the allowability of Claim 29. These dependent claims carry some of the features of the original claims presently under examination.

Reconsideration of the Examiner's rejection of Claims 1, 2, 11, 14, 21 and 29 under 35 U.S.C. 102(b) as allegedly being anticipated by Genese is respectfully requested. Claim 1 of the instant application calls for an assembly for transferring fluid between a vessel having a body with a neck at one end thereof and with an open end and a slidable piston positioned within the body, and a vial having a penetrable seal. In interpreting the claim and the reference of Genese, it would appear that the proper interpretation is one wherein the equivalent of the vial in Claim 1 is a container 42 on the right hand side of Figures 1 to 3 of Genese and the vessel defined in Claim 1 is that shown and designated by reference numeral 18 on the left hand side of the Figures.

Claim 1 calls for a housing having first and second open ends, a bore extending between the first and second open ends, and the housing being removably connected to the piston (designated by reference numeral 30 in Figure 1 of the instant application with the housing means designated by reference numeral 42). As will be clearly seen from Figures 1 to 3, housing 10 of Genese is not connected to a piston of container 18.

Claim 1 further calls for a vial socket assembly having a vial socket for receiving and engaging a neck of the vial. Again, Genese does not disclose such an arrangement; the drawings clearly show that the housing (and not the vial socket assembly) is connected to the plunger or piston of Genese.

Genese transfers a diluent from one container into a second container containing the active ingredient. This is then transferred back into the first container which functions as a syringe for injection into the patient. The transfer is effected through the front end of both containers with the rear ends being completely sealed. This is opposed to Applicant's arrangement wherein the connection is between the rear end of the syringe and the front end of the vial.

The importance of this arrangement is related to the sterility aspects of the same. In Genese, the needle used for penetrating into the vial 42 is also the needle which will be used for injecting the patient. In the art, this is considered a far less satisfactory arrangement than that proposed by Applicant wherein a sterile needle can be connected at the front end of the syringe.

For the above reasons, it is respectfully submitted that Genese does not respond to the limitations of Claim 1. Claims 11 and 12 are also believed to add elements which are not shown in Genese. Thus, as previously mentioned, the vial socket retains the neck of

vial and not the plunger or piston as shown and taught by Genese.

Even assuming that the Examiner is interpreting the claim in the reverse manner, many of the same comments still apply. Thus, Genese would not disclose an arrangement wherein the vial socket receives and engages a neck of the vial. Also as mentioned above, the patent does not show an arrangement wherein the vessel has a body with a neck at one end thereof and with an open end and a slidable piston positioned within the body.

Applicant would also reiterate his previous comments with respect to the sterility aspects of the arrangement shown by Genese.

Claim 29 is believed to be clearly outside the scope of Genese. This claim calls for the combination of the syringe having a fluid within the syringe body and a slidable piston positioned within the body proximate the open end. A second end has a neck with a needle mount for removably mounting a needle thereon. With this claim, there can be no misinterpretation of which container is the syringe and which is the vial. The syringe contains the diluent to mix with the dry powder of Genese.

The rejection of Claim 14 under 35 U.S.C. 102(b) is respectfully traversed. Claim 14 calls for the vessel to be a syringe which has a neck with a needle mount for removably mounting a needle thereon and a flange adjacent the open end. The reason for this arrangement is set forth above. Clearly Genese does not show such an arrangement.

The rejection of Claim 21 under 35 U.S.C. 102(b) is also respectfully traversed. This claim calls for the vessel to be a cartridge which has a neck with a penetrable seal and a cap to retain the penetrable seal thereon. This arrangement is not seen in Genese.

The rejection of Claims 1 to 4, 9, 11 to 13, 21 and 29 under 35 U.S.C. 103(a) as allegedly being unpatentable over Haber et al in view of Genese is also respectfully

traversed.

The Examiner states that Haber et al discloses an assembly for transferring fluid between a vessel and a vial. Applicant would reiterate the arguments advanced in the previous amendment wherein Applicant stated that Haber et al discloses a device which is used to transfer a liquid from a glass ampule to a vial. The device of Haber et al teaches a transfer apparatus wherein the neck of the ampule is broken and the liquid transferred to the vial. Subsequent to this, a separate syringe is utilized for penetrating the septum of the vial for subsequent injection. This is a substantially different arrangement than that of Applicant as defined in Claim 1.

The Examiner has stated that Haber et al chose a slidable piston (between spaces 90 and 104 in Figure 3) removably connected to the housing. This is not the arrangement defined in Claim 1 which clearly sets forth that the slidable piston is within the vessel. As noted by the Examiner, Haber et al does not show any such piston.

The bore referred to by the Examiner is vial cup 92 which functions in a manner far differently than Applicant's device.

The Examiner has stated that Haber discloses a socket assembly (48, 58) for receiving a vial. This is clearly not the case; the numbers cited by the Examiner refer to the ampule base and to an O-ring; this does not relate to a vial as understood by those knowledgeable in the art. The hollow piercing member recited as being disclosed by item 53 is a piercing member for piercing the bottom of the ampule.

The Examiner's attempt to combine Haber and Genese is not understood. Both are so remote from the teachings of Applicant that it is not seen where any such combination is practical or operable. The Examiner has stated that it "would have been obvious to one of

ordinary skill in the art at the time of the invention to modify the transfer device of Haber with the piston enclosed in the vessel of Genese in order to provide a sealing means that allows fluid to be transferred through the conduit when the device is advanced to the second position". This is speculation by the Examiner and there is nothing within the four corners of either of the references to suggest that one would attempt such an arrangement. Indeed, it is not seen how such an arrangement would be desirable. Haber teaches that there is a septum 78 at the bottom of the ampule. It is not understood why one would wish to place a piston therein as there is already provided a sealing means.

The Examiner has rejected Claims 2 and 3 stating that the first end of the conduit has a piercing member which pierces the vessel and the aperture is an opening adjacent the tip of the piercing member.

As set forth above, the teachings of Haber et al are so remote from the assembly defined in Claim 1 that it is not understood how the interpretation given by the Examiner can remotely begin to read on Claim 1.

In Paragraph 10 of the Office Action, the Examiner states that the vial socket assembly of Haber et al comprises a post (36, 37) for receiving the second end of the conduit. Applicant is unable to locate any reference numeral 37 either in the drawings or disclosure of the cited reference. Reference numeral 36 refers to a disk-like portion of an eccentric element. Contrary to the Examiner's assertation, this is not located in a vial socket assembly (vial is number 10 in Figure 4). It will also be noted that the post 38 does not receive the second end of the conduit.

The Examiner has rejected Claim 9 stating that Haber discloses an aperture on the side wall of the conduit having a blunt end. The Examiner is respectfully requested to

point out which end of the conduit is blunt since both ends appear to have sharp tips for piercing.

With respect to Claims 11 to 13, the Examiner has stated that the retaining member includes a plurality of retaining latches (40, 44). The Patentee states that reference numeral 40 relates to a press ring and reference numeral 44 denotes a conical surface. It is not understood how the Examiner can equate these with "latches".

With respect to Claim 21, the Examiner states that Haber discloses that the vessel is a cartridge having a neck with a penetrable closure and a cap to retain the closure thereon. Applicant is unable to find any such structure and the Examiner is respectfully requested to point out where in the description such a structure is taught.

The Examiner has cited Safabash in rejecting Claims 5 and 6. As previously pointed out, Safabash discloses a transfer device which transfers medication from a vial to a reservoir. This is completely different from what Applicant proposes. The object of Safabash is to transfer the medicant which is already being mixed to a syringe or the like. The teachings of this reference cannot make up the basic deficiencies of the primary reference and indeed, there is nothing within the four corners of this patent which would enable one to function in a manner defined by Applicant.

With respect to the rejection of Claims 7, 8, 14 and 15 to 24, none of the secondary references remotely resemble the instant assembly and merely taking a part shown in one patent and attempting to show that such a structure could be implemented in a second device does not make up for the basic deficiencies of the primary references.

As Applicant pointed out in his previous amending letter, it has been established in the jurisprudence that the Examiner may not resort to speculation, unfounded assumption

or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. It is believed that the following jurisprudence is pertinent to the issues under consideration herein. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968).

It is respectfully submitted that the evidence adduced by the Examiner is insufficient to establish a prima facie case of obviousness. See In re Rijckaert, 9F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established by presenting evidence that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed combination or other modification. See In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Furthermore, the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Rejections based on 35 U.S.C. 103 must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art.

As set forth above, it is Applicant's position that none of the references, either singularly or in combination, disclose the claimed combination set forth in Claim 1. Furthermore, the rejections of the other Claims under 35 U.S.C. 103 are traversed on the grounds that the selection of various elements from the prior art do not support a rejection under 35 U.S.C. 103 since there is nothing within the four corners of these references which would lead one to the present invention save and except for Applicant's own

disclosure thereof.

For the reasons set forth above, it is respectfully submitted that all the claims in the instant application clearly and patentably define over the prior art and are allowable. Such action is respectfully solicited.

Respectfully,

Eric Fincham

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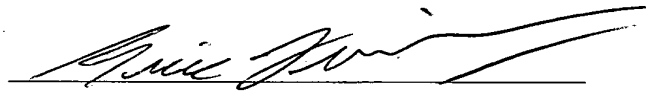

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